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11 UNITED STATES DISTRICT COURT  
12 FOR THE EASTERN DISTRICT OF WASHINGTON  
13

14 JEREMY OLSEN,

15 Plaintiff,

16 v.

17 XAVIER BECERRA, in his official  
18 capacity as Secretary of the United States  
19 Department of Health and Human  
20 Services,

21 Defendant.  
22

No. 2:21-CV-00326-SMJ

NOTICE OF SUPPLEMENTAL  
AUTHORITY IN SUPPORT OF  
DEFENDANT’S OPPOSITION TO  
MOTION FOR PRELIMINARY  
INJUNCTION

23 Defendant Xavier Becerra, in his official capacity as Secretary of the United  
24 States Department of Health and Human Services, (“Defendant”), through counsel,  
25 submits as supplemental authority in support of his response to Plaintiff’s motion for  
26 preliminary injunction (ECF No. 18), a Technical Direction Letter issued by the  
27 Centers for Medicare and Medicaid Services on today’s date (“**TDL-220257**”),  
28 attached hereto as **Appendix A**.

1 In relevant part, TDL-220257 directs Durable Medical Equipment Medicare  
2 Administrative Contractors (“DME MACs”) to apply the DME Final Rule referenced  
3 in Defendant’s preliminary injunction response (ECF No. 18 at 4-5, 7-8, 11), to claims  
4 with dates of service that predate the February 28, 2022 effective date of the DME  
5 Final Rule.  
6

7 In particular, TDL-220257 provides:  
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9 The [DME Final Rule] replaced a 2017 CMS Ruling, CMS-1682-R (“2017  
10 Ruling”), regarding CGMs. Pursuant to this TDL, the DME MACs shall  
11 apply the coverage and payment provisions of the [DME Final Rule] to valid  
12 reimbursement claims and appeals for CGM monitors or receivers and/or  
13 necessary supplies and accessories supplied prior to February 28, 2022. The  
14 [DME Final Rule] obviates the need for further application of the 2017  
15 Ruling on CGMs, as CMS has determined that, in addition to therapeutic or  
16 non-adjunctive CGMs, non-therapeutic or adjunctive CGMs can also meet  
17 the Medicare definition of durable medical equipment (DME) at 42 C.F.R. §  
18 414.402. Applying the coverage and payment provisions of the [DME Final  
19 Rule] to valid reimbursement claims and appeals for CGM monitors or  
20 receivers and/or necessary supplies and accessories supplied prior to  
21 February 28, 2022 will avoid expending administrative resources on further  
22 application of the 2017 Ruling on CGMs and additional appeals challenging  
23 application of the 2017 Ruling.

24 \* \* \*

25 The DME MACs shall apply the direction in this TDL to CGM monitors or  
26 receivers and/or their necessary supplies and accessories supplied to a  
27 beneficiary before the February 28, 2022 effective date of the [DME Final  
28 Rule] where either (1) a valid reimbursement claim or valid appeal is  
pending as of February 28, 2022; or (2) the right to submit a valid  
reimbursement claim or file a valid appeal has not expired as of February 28,  
2022.

TDL-220257 at 1-2, 2-3 (emphasis added).

Plaintiff’s motion asks this court to enter a preliminary injunction “barring the

1 Secretary from continuing to reject continuous glucose monitor (CGM) claims based  
2 on CMS 1682-R and/or the claim that a CGM is not ‘primarily and customarily used  
3 to serve a medical purpose.’” ECF No. 6 at 1. TDL-220257 makes clear that the  
4 Secretary has superseded CMS 1682-R, and the Secretary’s contractors will no longer  
5 be relying on it to deny CGM claims as of TDL-220257’s effective date of February  
6 28, 2022. It further demonstrates that the Secretary’s contractors will no longer deny  
7 CGM claims based on the notion that a CGM is not “primarily and customarily used  
8 to serve a medical purpose.” This is so because the DME Final Rule considers CGMs  
9 to be “primarily and customarily used to serve a medical purpose,” *see* 86 Fed. Reg. at  
10 73,899, and TDL-220257 incorporates the DME Final Rule and instructs the DME  
11 MACs to apply its coverage and payment provisions to valid claims and appeals for  
12 CGM monitors or receivers and/or necessary supplies and accessories supplied prior  
13 to February 28, 2022. Thus, TDL-220257 serves to further moot Plaintiff’s pending  
14 preliminary injunction motion. *See* ECF No. 18 at 6–9.

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20 Indeed, TDL-220257 eliminates the possibility that CGM claims that predate  
21 the effective date of the DME Final Rule will be denied by the Secretary’s contractors  
22 on the basis of CMS 1682-R. The Secretary has instructed his contractors, as of TDL-  
23 220257’s effective date of February 28, 2022, that they may no longer rely upon CMS  
24 1682-R as a basis for denying CGM claims.

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1 DATED this 25th day of February, 2022.

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 25, 2022, I caused to be delivered via the method listed below the document to which this Certificate of Service is attached (plus any exhibits and/or attachments) to the following:

| <b>NAME &amp; ADDRESS</b>   | <b>Method of Delivery</b>  |
|---|--|
| Roger Townsend<br>BRESKIN JOHNSON TOWNSEND<br>1000 Second Ave., Suite 3670<br>Seattle, WA 98104 | <input checked="" type="checkbox"/> CM/ECF System<br><input type="checkbox"/> Electronic Mail<br><input type="checkbox"/> U.S. Mail<br><input type="checkbox"/> Other: _____ |
| James Pistorino<br>PARRISH LAW OFFICES<br>788 Washington Road<br>Pittsburgh, PA 15228           | <input checked="" type="checkbox"/> CM/ECF System<br><input type="checkbox"/> Electronic Mail<br><input type="checkbox"/> U.S. Mail<br><input type="checkbox"/> Other: _____ |

s/John T. Drake  
John T. Drake